REMARKS

Claims 1-5, 7, 10, and 12-14 are pending in the subject application.

Claims 1-5, 7 and 10 have been amended to more clearly define the claimed subject matter. No new matter has been added by the amendments. Support for the amendments is found throughout the application and claims as originally filed.

It is submitted that the claims, herewith and as originally presented, are patentably distinct over the prior art cited by the Examiner, and that these claims were in full compliance with the requirements of 35 U.S.C. § 112. Reconsideration and withdrawal of the objections to and the rejections of this application in view of the remarks herewith, are respectfully requested, as the application is believed to be in condition for allowance.

Applicants respectfully reserve the right to pursue any non-elected, canceled or otherwise unclaimed subject matter in one or more continuation, continuation-in-part, or divisional applications.

Rejections under 35 U.S.C. § 112, Second Paragraph

Claim 7 stands rejected because the term "medicament" is allegedly unclear and because the claim is allegedly "self-conflicting". Without conceding the validity of the rejection, Claim 7 has been amended to recite a "pharmaceutical composition" instead of a "medicament". Furthermore, claim 7 has been amended to delete the "essentially nontoxic" language.

Claim 7 is directed to a composition comprising at least one compound of the invention mixed with at least one pharmaceutically acceptable carrier or

excipient. The composition can comprise any amount of each ingredient as well as any other ingredients (as evidenced by the "comprising" language.) Applicants respectfully disagree with the Examiner's contention that a pharmaceutical composition by definition must be "effective yet non-toxic." While the composition is useful as a pharmaceutical, Applicants respectfully assert that no effective dosage limitation is required for Claim 7. Indeed, the language and meaning of claim 7 as amended is not indefinite and Applicants respectfully request reconsideration and withdrawal of these rejections.

Rejections under 35 U.S.C. § 112, First Paragraph

Claims 1-5, 7, 10, and 12-14 stand rejected as failing to "reasonably provide enablement making solvates and hydrates of the claimed invention."

Without conceding the validity of the Examiner's rejections, claims 1-4 have been amended to recite "or a salt thereof" instead of "or the salts, solvates or solvates of the salts thereof". Similarly, claim 5 has been amended to remove the solvate and solvate of salts language. Applicants respectfully request reconsideration and withdrawal of these rejections.

Claim 10 stand rejected as failing to reasonably provide enablement for the treatment or prevention of impairments of perception, concentration, learning and/or memory. Applicants respectfully disagree.

As an initial matter, although Applicants strongly disagree with the Examiner's allegation that the specification is viewed as lacking enablement for prevention of any of the impairments recited, the pending claim have been amended to delete the terms of "and/or prophylaxis," solely to expedite the prosecution of the present application, and without prejudice to Applicants' right to pursue them in one or more continuation, divisional or continuation-in-part applications. In view of these amendments and the following discussions, Applicants respectfully submit that the rejection must be withdrawn.

With regard to the methods of treatment defined by the present claims, the test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation. *U.S. v. Telectronics, Inc.*, 857 F.2d 778, 785 (Fed. Cir. 1988). The examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention. Manual of Patent Examining Procedure ("MPEP") § 2164.04 (citing *In re Wright*, 999 F.2d 1557, 1562 (Fed. Cir. 1993)).

Accordingly:

> A specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented *must be taken as being in compliance with the enablement requirement ... unless there is a reason to doubt the objective truth of the statements contained therein* which must be relied on for enabling support
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> * * *

> It is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement.
> *Id. (emphases added).*

Applicants respectfully submit that whether or not the scope of a claim is broad is irrelevant to the assessment of the enablement of the claim. The question is whether those skilled in the art would have been able to make and use the claimed invention based on the disclosure. (See *U.S. v. Telectronics, Inc., at 785*).

Applicants respectfully submit that the pending claims are enabled because the specification "contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented." *Id.*

Nonetheless, the Examiner further alleges that one skilled in the art would have to engage in an undue amount of experimentation to use the instantly claimed invention commensurate in scope with the claims. Applicants respectfully disagree with these allegations.

The specification states, by way of example, that the compounds according to the invention are selective ligands, especially agonists, of α7 nAChR and that "α7 nAChR has a particularly high permeability for calcium ions, increases glutamatergic neurotransmission, influences the growth of axons and... modulates neuronal plasticity" (Pate 1, lines 24-27). The specification further provides the procedures for determining the affinity of test substances for α7 nAChR as well as protocols for object recognition and social recognition animal model tests which can

be readily utilized by one of skill in the art to assess a particular compound for use in the treatment of impairments of perception, concentration, learning and/or memory.

Similarly, it is disclosed that the claimed compounds can be prepared by synthetic procedures described in the specification at, for example, Page 7, line 18-Page 9, line 14; and using the materials and procedures described on Pages 9-12.

Therefore, it is clear that sufficient guidance is provided in the specification to allow those of ordinary skill in the art to make and use the claimed invention, as required by 35 U.S.C. § 112, first paragraph.

Furthermore, the determination by a physician as to whether a claimed compound is effective in treating a recited condition in a given patient is a type of determination that is always made by physicians for every pharmaceutical. Indeed, the determination is a routine one that every physician is prepared to make, and which requires little or no effort.

Applicants respectfully submit that one reasonably skilled in the art could make or use the invention as claimed without undue experimentation. Therefore, Applicants respectfully request that the rejection of the claims under 35 U.S.C. § 112, first paragraph be reconsidered and withdrawn.

CONCLUSION

In view of the amendments and remarks made herein, the application is believed to be in condition for allowance. Favorable reconsideration of the application and prompt issuance of a Notice of Allowance are respectfully requested. Please charge any required fee or credit any overpayment to Deposit Account No. 04-1105.

Respectfully submitted,

Date: August 17, 2007

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